

**REMARKS/ARGUMENTS**

Claim 1 has been amended. Thus, Claims 1-18 are pending with Claims 1 and 12 being the independent claims.

The Examiner has rejected Claims 1-11 and 12-18 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0229314 (McWethy, et al.). With particular regard to Claim 1, the Examiner states:

...McWethy discloses an injection device (Figs. 1-6) comprising: a housing (Fig. 2, 50) having a proximate end (near 52) and a distal end (near 51), the distal end having an opening therein (near 51); a cartridge barrel (30) within the housing, the cartridge barrel having proximate and distal ends; a needle cannula (within 13) fixed to the distal end of the cartridge barrel (Figs. 1 and 4); a stopper (Fig. 4, 38) within the cartridge barrel; a driver (42) coupled to the stopper; a shield (20) coupled to the housing and slidable between a retracted position (Figs. 1, 4 and 5) and an extended position (Fig. 6); shield driver means (24) activatable to urge the shield from the retracted position to the extended position; and sensor means (46) forming a portion of said driver (46) is connected and forms a portion of driver (42) and in slidable contact with an interior surface of the housing (Fig. 5 discloses that 46/sensor means detects an end profile of the housing (46 detects 54 which is being interpreted as the end profile of the housing. Please note that Applicant has not specified which end of the housing it must sense/contact) and this trigger the release of 26 which automatically triggers the activation of the shield driver means upon detection. (Office Action, p. 2-3 of Sept. 5, 2008).

Applicants respectfully disagree for the following reasons.

The injector of McWethy specifies the retraction of the needle 12 and cartridge 30 rearwardly into the device upon completion of the drug delivery:

[0029] The needle 12 and cartridge 30 are maintained in axial alignment with barrel 20 by a cartridge holder 50 disposed between the cartridge and the inside wall of the barrel. A compression spring 24 circumscribes the forward end of cartridge holder 50 and is compressed against the interior of the barrel 30 at the barrel's forward end. The rearward end of spring 24 bears against the forward end of cartridge holder 50 to bias cartridge holder and needle 12 in the rearward direction. After the completion of an injection stroke, spring 24 expands to displace the cartridge holder 50, needle 12 and cartridge 30 rearwardly into the device. The barrel 20 and cartridge holder 50 are preferably formed of a transparent or translucent plastic material. (emphasis added, McWethy).

[0045] As retaining arms 26 are deflected outwardly, latches 27 are gradually displaced from the engaged position to a released position, as illustrated in FIG. 5. In the released position, latches 27 are deflected outwardly from barrel 20, disengaging the flange 54 on cartridge holder 50. Plunger collar 46 is aligned longitudinally with flange 54 such that the forward edge of the collar contacts the rear edge of the flange as latches 27 are displaced out of engagement with the flange. As such, latches 27 no longer maintain cartridge holder 50 toward the forward end of barrel 20 against the bias of spring 24. Rather, cartridge holder 50 is maintained in the forward end of the barrel 20 against the bias of spring 24 by axial pressure applied on finger pad 44 and plunger collar 46. Upon removal of axial pressure on finger pad 44 and collar 46, the force exerted by spring 24 on cartridge holder 50 is no longer counteracted, allowing spring 24 to expand and displace the cartridge holder rearwardly into the barrel 20, as shown in FIG. 5. (emphasis added, McWethy).

Among other things, McWethy fails to disclose several elements of Claim 1: a shield coupled to the housing and slidable between a retracted and an extended position and also fails to disclose a shield driver means that urges the shield from a retracted position to an extended position. In addition, there is no sensor means in McWethy that detects the end profile of the cartridge barrel. In fact, the collar 46 makes no contact at all with the cartridge barrel 30 in McWethy so there is no detection of the “end of the barrel” as specified in Claim 1. Rather, in McWethy, it is simply the plunger collar 46 displacing the latches 27 of the retaining arms 26 away from the cartridge holder flange 54 that allows the spring 24 to drive the cartridge holder 50 rearwardly into the barrel 20. See paragraph 0045 of McWethy above. Furthermore, Claim 1 has been amended to no longer specify the detection of the end profile of the housing. Thus, in view of the foregoing, Applicants respectfully submit that Claim 1 is now patentable over the art of record.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 3 is dependent upon Claim 2 and is patentable for the same reasons.

Claim 4 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the Examiner has identified spring 24 as meeting the limitation of the shield driver means. However, the spring 24 of McWethy is not arranged to be manually pushed through the housing. Rather, the spring 24 remains compressed until the collar 46 releases the spring bias. Thus, for all of these reasons, Claim 4 is patentable over the art of record.

Claim 5 is dependent upon Claim 4 and is patentable for the same reasons. Furthermore, as specified in Claim 5, the coil spring and the driver are distinct elements. Thus, the Examiner's identification of spring 24 of McWethy as meeting the limitation of the shield driver means cannot also meet the limitation of the coil spring. Thus, for all of these reasons, Claim 5 is patentable over the art of record.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 7 is dependent upon Claim 6 and is patentable for the same reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons. In addition, as mentioned earlier, the Examiner equates the spring 24 of McWethy with the driver of the present invention. However, there are no deformable arms attached or formed integrally with the spring 24 in McWethy. Thus, for all of these reasons, Claim 8 is patentable over the art of record.

Claim 9 is dependent upon Claim 8 and is patentable for the same reasons. Furthermore, it is not clear what part of McWethy depicts "arms biased against the exterior surface of the cartridge barrel." If the latches 27 are meant to meet this limitation, as mentioned previously, these make no contact with the barrel 30 in McWethy. Thus, for all of these reasons, Claim 9 is

patentable over the art of record.

Claim 10 is dependent upon Claim 8 and is patentable for the same reasons.

Claim 11 is dependent upon Claim 1 and is patentable for the same reasons. Moreover, as mentioned previously, the Examiner equates the spring 24 of McWethy as the driver specified in the claims. However, it is unclear where in Fig. 5 of McWethy, the spring 24 is shown as a single molded plastic element which includes the sensor means. Thus, for all of these reasons, Claim 11 is patentable over the art of record.

With particular regard to Claim 12, the Examiner states:

...McWethy discloses an injection device (Figs. 1-6) comprising: a cartridge barrel (30), said barrel arranged to contain a stopper (Fig. 4, 38) and fluid therein and wherein said barrel has a second open end and a second open and a second end having a radial flange adjacent to the second end (Fig. 4, flange 54); a needle cannula (12) having a sharp distal end and a second open end, the fluid being in communication with said needle second end; a housing (50) surrounding said barrel, said housing having a distal open end adjacent the needle and a proximate end having a flange receiving the radial flange of the barrel; a shield (20) releasably retained by the housing, said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (Fig. 4); a driver (42), said driver positioned partially within said housing, said driver equipped with at least one deformable side arm (46) sensing the end of the barrel (Fig. 5 discloses that 46 detects 54 which is at the end of the barrel. Please note that Applicant has not claimed which end of the barrel must be sensed), said driver slidably located within said housing for moving the stopper forward (Fig. 5); and a biasing spring (24), said biasing spring further adapted to bias the shield to automatically cover the needle after said driver detects the end of the barrel (Fig. 5 discloses that when 46 contacts/senses 54 (the end of the barrel) this releases 26 which automatically releases the shield to cover the needle). (Office Action, p. 4-5 of Sept. 5, 2008).

Applicants respectfully disagree for the following reasons.

The Examiner equates the housing and shield specified in Claim 12, with the cartridge holder 50 and the hollow cylindrical barrel 20 of McWethy. However, in contravention to Claim 12, the hollow cylindrical barrel 20 slides over the cartridge holder 50, as can be most easily

seen in Figs. 5-6. Thus, based on McWethy, the housing (i.e., holder 50) is positioned primarily within the shield (i.e., the barrel 20) which is just the opposite of what Claim 12 specifies.

Moreover, it is unclear what part of the plunger collar 46 is deformable since McWethy does not include any teaching or suggestion that the collar 46 is deformable. If anything, the collar 46 most likely is a rigid element because that element needs to displace the latches 27 to release the bias against the spring 24; were the collar 46 deformable, this would impede releasing the spring 24 bias and degrade the operation of the McWethy injector. Furthermore, the collar 46 does not sense the end of the barrel. As mentioned previously with respect to Claim 1, the collar 46 makes no contact with the cartridge 30. Rather, the collar 46 contacts and displaces the latches 27 and eventually contacts the flange 54 of the holder 50. Thus, because the collar 46 of the driver 42 makes no contact with the barrel 30, the collar 46, nor the driver 42, also do not sense the end of the barrel. Thus, in view of the foregoing, Applicants respectfully submit that Claim 12 is patentable over the art of record.

Claim 13 is dependent upon Claim 12 and is patentable for the same reasons. In addition, in McWethy, the biasing spring 24 is not carried by the driver 42. In fact, biasing spring 24 makes no contact with the driver 42. Thus, for all of these reasons, Claim 13 is patentable over the art of record.

Claim 14 is dependent upon Claim 12 and is patentable for the same reasons. Furthermore, it is unclear where in Figs. 2 and 5 of McWethy, there are two sensor elements shown. Thus, for all of these reasons, Claim 14 is patentable over the art of record.

Claim 15 is dependent upon Claim 12 and is patentable for the same reasons.

Claim 16 is dependent upon Claim 15 and is patentable for the same reasons.

Claim 17 is dependent upon Claim 15 and is patentable for the same reasons.

Claim 18 is dependent upon Claim 1 and is patentable for the same reasons.

The Examiner has provisionally rejected Claims 1-18 based on obviousness-type double patenting as being unpatentable over Claims 1-70 of copending Application Serial No. 10/566,333. To that end, Applicants submit herewith a Terminal Disclaimer to overcome that rejection.

The Examiner has also provisionally-rejected Claims 1-18 on obviousness-type double patenting as being unpatentable over Claims 1-45 of Application Serial No. 10/899,923. However, this application has been expressly abandoned and therefore the obviousness-type double patenting rejection is rendered moot.

The Examiner has also provisionally-rejected Claims 1-18 on obviousness-type double patenting as being unpatentable over Claims 1-24 of Application Serial No. 11/666,851.

Applicants traverse this double patenting rejection based on the following reasons. The invention of ASN 11/666,851, among other things, does not include any sensor means, or any at least one deformable side arm, that detects an end profile of the barrel or housing, as is specified in Claims 1 and 12 of the present application. Thus, the present invention is patently distinct from the invention of ASN 11/666,851.

Thus, Applicants respectfully submit that, as amended, Claims 1-18 are now in condition for allowance. Accordingly, prompt and favorable examination on the merits is respectfully requested.

Application Serial No. 10/566,226  
Attorney Docket No. S2082/20003  
Amendment Dated December 24, 2008

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

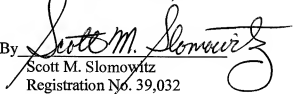
Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

December 24, 2008

Please charge or credit our  
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